

OCT 27 2006

Biotronics3D™
*Medicine in Three Dimensions***510(k) SUMMARY**

This summary of 510(k) safety and efficiency information has been submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is

1. Submitter's identification:

Biotronics3D Ltd.
31 Ferry Street
Isle of Dogs
Docklands
London E14 3DT
UK

Contact: Dr Haralambos Hatzakis, Managing Director.

Date Summary prepared: 15 May 2006.

2. Name of Device

- a) Device trade name: 3Dnet Suite.
- b) Device common name: Medical Image Processing software system.
- c) Classification name: LLZ – Image processing system Class II, CFR 21 892.2050.

3. Predicate Device Information:

Predicate Device #1: Bio-Vascular, Inc., Advanced Diagnostic Viewer (ADV), 510(k) #K963697

Predicate Device #2 : Voxar Limited, Plug n View, version 1.0, 510(k) #K992654

4. Device Description :

The 3Dnet Suite is a software device for evaluating scanned images of selected human organ. The basic visualization module of 3Dnet Suite is Examiner.

The Examiner allows the processing, review, analysis, communication and media interchange of multi dimensional digital images acquired from a variety of imaging devices.

It provides multi-dimensional visualization of digital images to aid clinicians in their analysis of anatomy and pathology. The 3Dnet user interface follows typical clinical workflow patterns to process, review and analyze digital images including:

- Retrieve image data over the network via DICOM
- Select images for closer examination from a gallery of 2D and 3D views
- Interactively manipulate an image in real time to visualize anatomy and pathology
- Annotate, tag, measure and record selected views

- Output selected views to DICOM and JPEG files or export views to another DICOM device.

5. Indications for use:

The 3Dnet Suite is intended to be used by physicians for the display of 2D/3D visualization of DICOM compliant medical image data, such as CT, MRI, and Ultrasound scans.

The 3Dnet Suite provides several levels of functionality to the user:

- basic analysis tools they use on a daily basis such as 2D review, orthogonal multiplanar reconstructions (MPR), oblique MPR, curved MPR, Slab MPR AvgIP, MIP, MinIP, measurements, annotations, reporting, distribution etc.
- tools for in-depth analysis, such as segmentation, endoscopic review, color VR slab, grayscale VR slab, 3D volume review, path definition and boundary detection etc.
- Specialist tools and workflow enhancements for specific clinical applications which provide target workflows, custom UI, targeted measurement and visualization, including colon screening which is indented for the screening of patients for colonic polyps, tumors and other lesions using tomographic colonography.

6. Comparison to predicate devices:

The 3Dnet Suite utilizes the same technological characteristics as the two predicate devices. All provide multi-view user interfaces with combinations of 2D and 3D views correlated together for enhanced visualization. All provide window/level adjustment of the 2D and 3D views to enhance features, provide measurement tools for analysis of the observed structures, provide region of interest tools to isolate specific features and provide annotation tools to help indicate and describe findings.

All devices support the DICOM protocol for the communication of images with other medical devices.

Substantial Equivalence Comparison Chart

Company	Biotronics3D	Voxar Limited	Bio-Vascular, Inc.
System	3Dnet Suite	Plug n View, version 1.0	Advanced Diagnostic Viewer (ADV)
510(k) no:		K992654	K963697
Function:	<ul style="list-style-type: none"> • 2D/3D image viewing • Segmentation • Measurements • Data Analysis • Multi-Planar reformatting (MPR) 	<ul style="list-style-type: none"> • 2D image viewing • Measurement • Multi-Planar reformatting (MPR) 	<ul style="list-style-type: none"> • Display • Segmentation • Manual Measurements • Data analysis • Archive

	<ul style="list-style-type: none"> • Volume rendering • Maximum Intensity Projection (MIP) • Image Editing • Printing 	<ul style="list-style-type: none"> • Volume rendering • Maximum Intensity Projection (MIP) • Image Editing • Printing 	
Intended Use:	Display of 2D/3D visualization of DICOM compliant medical image data, such as CT, MRI, and Ultrasound scans.	Display and 3D visualization of medical image data derived from CT and MRI scans.	Create 2D,3D images of the anatomy for clinician viewing analysis
Data Source:	MR,CT,3D US scanners	MR, CT, NM, CR, and US Scanners	MR, CT Scanners
Physical Characterization:	Software package <ul style="list-style-type: none"> • Operates on off the self hardware • Windows operating system • DICOM compatible 	Software package <ul style="list-style-type: none"> • Operates on off the self hardware • Windows operating system • DICOM compatible 	Software package <ul style="list-style-type: none"> • Operates on off the self hardware • Windows operating system • DICOM compatible

We conclude that the subject device, the 3Dnet Suite, is as safe and effective as the predicate devices and poses no new questions of safety and effectiveness.

7. Discussion of non-clinical tests performed for the determination of substantial equivalence are as follows:

Scanned image datasets of various patient organs with known abnormalities or status used as input for testing of software functionalities in accordance with a test protocol. The application provided interactive orthogonal and multiplanar reformatted 2D and 3D image from datasets to detect and evaluate the known abnormalities or status of organs. The volume, linear and angular measurements features, provided in the software, were used to evaluate and quantify any abnormality of organs or status of any internal organ structures. The 3Dnet Suite has been developed in a manner consistent with accepted standards for software development, including both unit and system integration testing protocols. Testing of phantom datasets has determined its level of accuracy, which correlates perfectly with pre-calculated values. The product has shown itself to be reliable, easy to use and capable of evaluating DICOM compliant scanned images of any human organs. We conclude from these tests that 3Dnet Suite is substantially equivalent to the predicated devices in its ability to evaluate any human organs.

8. Conclusions:

The 3Dnet Suite has the same intended use and similar technological characteristics as the Bio-Vascular, Inc., Advanced Diagnostic Viewer (ADV), (#K963697) and Voxar Limited, Plug n View 3D, version 1.0 (#K992654). Moreover, test and validations using Patients Image Data in our installations in Europe and non-clinical tests performed in-house demonstrated that the 3Dnet Suite is substantially equivalent to the predicate devices in its ability to review, analyze and evaluate DICOM scan images of various organs to facilitate analysis and evaluation of abnormality or malformation in organs by a trained user. The DICOM functionality with regards to DICOM SOP classes as stated in the DICOM conformance statement was validated with a number of other DICOM compliant applications and DICOM validation tools as part of the development and testing process. 3Dnet Suite does not raise any new questions of safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

OCT 27 2006

Biotronics 3D, Ltd.
% Ms. Patricia L. Murphy
Official Correspondent
KEMA Quality B.V.
4377 County Line Road
CHALFONT PA 18914

Re: K063107

Trade/Device Name: 3Dnet Suite
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 4, 2006
Received: October 11, 2006

Dear Ms. Murphy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

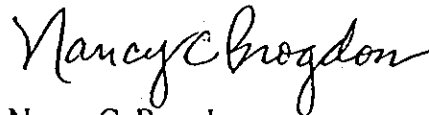
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063107

Device Name: 3Dnet Suite

Indications For Use:

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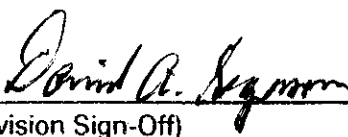
Prescription Use X
(Part 21 CFR 801 Subpart D)

~~AND/OR~~

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063107

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